

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

12669



1 - AFFIDAVITS

**000001**

## AFFIDAVIT

SAMPLE NO.

STATE OF

COUNTY OF

Before me, Iris MacInnes, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 966 (20 U.S.C. 3503), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared [REDACTED] in the county and State aforesaid, who, being duly sworn, deposes and says:

I am [REDACTED] and I reside at [REDACTED]. On 10/29/97, I met with FDA Investigator Iris MacInnes to discuss my complaint against the firm [REDACTED] located at [REDACTED]. FDA Investigator Iris MacInnes asked if I would explain the circumstances that lead up to the complaint.

On or about 11/21/96 I visited the firm called the [REDACTED] located at [REDACTED]. At the time of my visit I was interviewed by a technician named [REDACTED] (no last name). I was asked questions about my health and I informed the technician that I had a family history of heart problems. The technician asked if I personally had any heart problems and I stated that I did not. She then instructed me to answer 'NO' on my health history questionnaire regarding heart problems.

I was then told that the program included a diet plan, food supplements, dietary supplements, and vitamins. The dietary supplements were natural herbs that would naturally increase my metabolism to help me loss weight.

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Subscribed and sworn to before me at [REDACTED]

(City and State)

this thirty-first day of October, 1997.

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Iris MacInnes  
(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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At no time during the interview was I told that the dietary supplements, i.e., Herbal Balance contained Ephedra or Ma Huang. I was never told that this product caused any side-effects.

After I paid the program fee of about \$1,400.00, I began the program. I was told by the \_\_\_\_\_ technician to take \_\_\_\_\_  
one (1) Herbal Balance capsules three (3) times a day plus one  
two (2) \_\_\_\_\_  
(1) multivitamin. I was also given food supplements, i.e., powdered drinks, soups, and food bars. They told me that after one week they would increase the dosage of the Herbal Balance to \_\_\_\_\_  
two (2) capsules three times a day. They said that by increasing the dosage every week would acclimate my body to the dosage which would increase my metabolism.

During the program, I was going into the clinic on a daily basis. These visits included checking my weight, taking my blood pressure, and checking my measurements. The first week on the program I noticed that I had more energy. But the second week was insane. This was when I began having unusual side-effects.

Subscribed and sworn to before me at \_\_\_\_\_

(City and State)

this thirty-first day of October, 1997

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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## AFFIDAVIT

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Before I started the program I sleep at least nine hours a day. By the second week on the program I was suffering from insomnia. At one point, I did not sleep for almost 72 hours. I could not sleep even though I was tired. I also suffered from heart palpitations, shakes, difficulty breathing, hot flashes, sweating, and increased heart rate.

On one of my daily visits to the [REDACTED] I told the technician about the side-effects I was having. The technician told me it was due to stress. I was told that the Herbal Balance was safe and would not cause the symptoms I was describing. Because I thought the technicians at the clinic were medically trained, I believed them. The technician went on to say that I should increase my dosage because I would acclimate faster, and my metabolism would increase sooner. I did not tell them that I had already decreased my dosage to one capsule, three times a day.

I continued on the diet program and requested that my records be transferred to the [REDACTED] located at [REDACTED]. I was starting my Christmas Break (12/96 thru 1/97) and planned to spend it at home located [REDACTED].

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Subscribed and sworn to before me at [REDACTED] (City and State)

this thirty-first day of October, 19 97.

Iris MacInnes  
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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at [REDACTED] It was during my Christmas Break that I talked to my aunt who sells vitamins.

Before I could even discuss my side-effects, she told me that if the product had Ma Huang or Ephedra to stop taking it. I told her that it did have Ma Huang in it. She told me that it contained Ephedra which was a naturally occurring amphetamine. As a result of my conversation with my aunt, I stopped taking the Herbal Balance.

After talking to my aunt, I spoke to Dr. [REDACTED] specializing in Pharmacology and Drug Law. Dr. [REDACTED] provided me with information on products containing Ma Huang and Ephedra. [REDACTED] also spoke to Mr. [REDACTED] a people's lawyer in [REDACTED]. It was Mr. [REDACTED] who informed me that the [REDACTED] had been deceptive in not informing me that the product, Herbal Balance contained Ephedra which is an amphetamine. If I had known that the Herbal Balance contained amphetamines I would not have signed up for the program or have taken the capsules. I did not see a medical physician about my side-effects.

Subscribed and sworn to before me at [REDACTED] (City and State)  
this thirty-first day of October, 19 97.

Iris MacInnes  
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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<p>Before me, <u>Iris MacInnes</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-16, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 609, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared _____ in the county and State aforesaid, who, being duly sworn, deposes and says:</p> <p>I then contacted the _____ and asked for my money back. I told them that they had been deceptive in not informing me that the Herbal Balance had amphetamines. I told them that they had not disclosed crucial information about Herbal Balance or it's side-effects which was a false and deceptive practice under the _____.</p> <p>_____ At that time, the firm offered me a small return of the program fee. I declined the offer.</p> <p>I decided to take the firm to small claims court. Under the _____ I was required to give the firm sixty days notice of my complaint prior to filing my claim. On 12/18/98, I sent the firm a letter requesting reimbursement of the program fee. I hand-delivered a copy of the letter to the _____ located at _____.</p> <p>_____ I also sent a certified letter to the _____ in care of Ms. _____.</p> <p>_____ I did not receive any response to my correspondence.</p> <p>As a result, I filed a claim in Small Claims Court on or about 8/20/97. As of 9/19/97 I have settled out of court with _____ for an undisclosed amount.</p>		
<p>Subscribed and sworn to before me at _____ (City and State) this <u>thirty-first</u> day of <u>October</u>, 19 <u>97</u>.</p> <p style="text-align: right;"><u>Iris MacInnes</u> (Employee's Signature)</p>		
<p>Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.</p>		

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I am providing this information in order to put a stop to the [REDACTED] doceptive practices and the side-effects caused by the dietary supplement called Herbal Balance which contains Ephedra.

I am also providing FDA Investigator MacInnes at no charge, a bottle of the dietary supplement labeled in part: "\*\*\*\*The Herbal Approach To Weight Loss\*\*\*\*Herbal Balance\*\*\*\*Sold Exclusively by Authorized Distributors\*\*\*\*180 Capsules\*\*\*\*INGREDIENTS:\*\*\*\*Ephedra sinica (Ma Huang stem,\*\*\*\*LOT#\*\*\*\*139601C\*\*\*\*EXP.\*\*\*5 98\*\*\*\* DISTRIBUTED BY: SLIM FOR LIFE, INC., PLANTATION, FL 33313\*\*\*\*".

I did tell FDA Investigator MacInnes that I knew of one other person, a Mr. [REDACTED] who had been on the [REDACTED] program. Mr. [REDACTED] was a high school friend who had lost weight while on the program. He was even the firm's spokesperson and was on the firm's TV commercials in 1986. It was the TV commercials that prompted me to join the program.

I did see Mr. [REDACTED] prior to joining the program. He had gained <sup>weight</sup> ~~about 80~~ pounds and stated that his metabolism was messed up. At that time, Mr. [REDACTED] continued to speak highly about the program. Now, however, I believe Mr. [REDACTED] was suffering from side-effects

Subscribed and sworn to before me at [REDACTED] (City and State)  
this thirty-first day of October, 1997.

Iris MacInnes  
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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of the dietary supplement which resulted in his problems with his metabolism.

This information was provided to the best of my knowledge.

[REDACTED]

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RECEIVED  
CLINICAL RES-A  
& REVIEW/OSN HFS-452

Subscribed and sworn to before me at [REDACTED] (City and State)

this thirty-first day of October, 19 97.

Iris MacInnes  
(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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